

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

EME S.r.l.

Via degli Abeti, 88/1

61122 Pesaro (PU) – Italy

has established and applies a quality management system
for the following scope:

**Design, manufacture and placing on the market of electromedical equipment for
physiotherapy, rehabilitation and aesthetic medicine.**

Through an Audit, Report No. 7991503010AF12, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 1232408**

This Certificate is valid from 2024/09/13 to 2024/12/27

The reference date for all the next audits is (day-month): 27/12

Milan, 2024/09/13. First Certification: 2011/02/01



The certification responsible: Daniele Ricchi
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of
the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or
Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



MS N° 0083

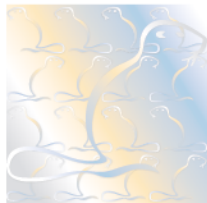
Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC.
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements.



Management
System
EN ISO
13485:2016

www.tuv.com
ID 9000034494





Reg. Number	8998 - A	Valid From	2021-12-23
First issue date	2011-02-01	Last change date	2021-12-23
Valid Until	2024-12-27	IAF Sector	19

Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

EME S.r.l.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, manufacturing of electromedical equipment for physiotherapy, rehabilitation and medical aesthetic sectors. Design, manufacturing of electronic equipment for aesthetic sectors.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

EME S.r.l.

Registered Headquarters

- Via degli Abeti, 88/1 61122 Pesaro Italia

Certified Sites

- Via degli Abeti, 88/1 61122 Pesaro Italia

DICHIARAZIONE DI
CONFORMITÀ ALLA
DIRETTIVA 93/42/CEE
SUI DISPOSITIVI MEDICI



Aesthetic & Medical Technologies

DECLARATION OF
CONFORMITY TO THE
93/42/CEE DIRECTIVE
ON MEDICAL DEVICES

Il Fabbricante / The manufacturer

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

dichiara sulla sua responsabilità che il prodotto :
declares on its own responsibility that the product :

Apparecchiature per magneto terapia /
Equipment for magneto therapy :

MAGNETOMED 7200 - MAGNETOMED 7400
MAGNETOMED 8400

è conforme alle prescrizioni della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche
(Allegato II eccetto il punto 4), recepita in Italia con
D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche ,
e la classe di rischio è la IIa secondo la regola 9.

is in compliance with the 93/42/CEE Directive and the following integrations and modifications
(Annex II except point 4) , implemented in Italy
following the D.L. N° 46 directive issued on 24 february 1997,
and the risk class is IIa according to the rule 9.

Certificato n. MED – 31009 / Certificate n. MED – 31009

La macchina è marcata / *The equipment is marked :*

CE 0476

Organismo Notificato / *Notified Body*
Kiwa Cermet Italia S.p.a.

Pesaro, 14/04/2016

EME srl
L'Amministratore unico / *Administrator*

DICHIARAZIONE DI
CONFORMITÀ ALLA
DIRETTIVA 93/42/CEE
SUI DISPOSITIVI MEDICI



Aesthetic & Medical Technologies

DECLARATION OF
CONFORMITY TO THE
93/42/CEE DIRECTIVE
ON MEDICAL DEVICES

Il Fabbricante / The manufacturer

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

**dichiara sulla sua responsabilità che il prodotto :
*declares on its own responsibility that the product :***

Apparecchiature per terapia ionoforesi ed elettrostimolazione /
Equipment for ionophoresis and electrostimulation therapy :

THERAPIC 9400 - THERAPIC 9200 - THERAPIC 7200

è conforme alle prescrizioni della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche
(Allegato II eccetto il punto 4), recepita in Italia con
D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche ,
e la classe di rischio è la IIb secondo la regola 9.

*is in compliance with the 93/42/CEE Directive and the following integrations and modifications
(Annex II except point 4), implemented in Italy
following the D.L. N° 46 directive issued on 24 february 1997,
and the risk class is IIb according to the rule 9.*

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Organismo Notificato / *Notified Body*
Kiwa Cermet Italia S.p.a.

Pesaro, 14/04/2016

EME srl
L'Amministratore unico / *Administrator*

TÜV Rheinland Italia S.r.l.
Sicurezza e Qualità Prodotto

TÜV Rheinland Italia S.r.l.
Via Mattei 3
20005 Pogliano Milanese (MI)
Italia

Via del Faggiolo 1/12
40132 Bologna
Italia

EME S.r.l.
**Registered and Operational
Headquarter:**
Via degli Abeti, 88/1
61122 Pesaro (PU)

Alla c.a.
Dott. Pieraccini Alessandro

Date: 24/05/2024

Object: Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Dott. Pieraccini

This letter confirms that, TUV RHEINLAND ITALIA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1936 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

EME S.r.l.
Registered and Operational Headquarter:
Via degli Abeti, 88/1
61122 Pesaro (PU)

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below

The table identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB

- has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive showed on Certificate no° MED 31009; for these device TUV Rheinland Italia will take the responsibility for appropriate surveillance from September 27th, 2024.

TÜV Rheinland Italia S.r.l.
Sede Legale ed operativa
Membro del Gruppo
TÜV Rheinland

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20005 Pogliano Milanese (MI)

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Fax: +39.02.939.687.23
E-mail:informazioni@it.tuv.com
Web:www.tuvitalia.com

Capitale sociale
EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

TÜV Rheinland Italia S.r.l.
Sicurezza e Qualità Prodotto

- has taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive showed on Certificate no° HD 60139851

In the case of devices covered by certificates issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Devices covered by this letter, and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received. For these device TUV Rheinland Italia will take the responsibility for appropriate surveillance from September 27th, 2024:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Radarmed 2500 CP	Class IIb	N/A	Certificate issued by Kiwa Cermet Italia S.p.A.
Microradar puls			Certificate no: MED 31009 Annex II except point 4
Combimed 4000			Date of issue 01/02/2011
Polyter Evo			Date of expiry 26/05/2024
KOMBY EXCELLENT			
Lasermed 2200			

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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medilaser PR999 4W PR999 8W Electromed 2 LMF Therapic 9200 Therapic 9400 Medison 1/3 Ultrasonic 1300 Ultrasonic 1500 Combimed 2200 Medicomb			
Magnetomed 7200 Magnetomed 8400 MEDI MAG 2 Magneto 2 Magneto 4 Mag Expert	Class IIa	N/A	Certificate issued by Kiwa Cermet Italia S.p.A. Certificate no: MED 31009 Annex II except point 4 Date of issue 01/02/2011 Date of expiry 26/05/2024
Devices covered by this letter, and for which the NB is responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received:			
Mo-Vit TLM Ref.code: MV001	Class IIa	N/A	Certificate issued by TÜV RHEINLAND ITALIA Certificate no: HD 60139851 Annex II except point 4 Date of issue 09/07/2019 Date of expiry 26/05/2024
SHOCK MED Ref.code: SW2050 SHOCK MED SP Ref.code: SW2051 HR TEK	Class IIb	N/A	Certificate issued by TÜV RHEINLAND ITALIA Certificate no: HD 60139851 Annex II except point 4 Date of issue 09/07/2019

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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ref.code: HT2043 HR TEK SP Ref.code: HT2044 CRYSTAL YAG Ref.code: HL2063 CRYSTAL YAG SP Ref.code: HL2065 BIPOWER LUX Ref.code. HL2062 BIPOWER LUX SP Ref.code: HL2064			Date of expiry 26/05/2024

TÜV RHEINLAND ITALIA (n.1936)

 Andrea Franceschini
 Project Manager

 Annex: Certificate No. HD 60139851 issued by TÜV RHEINLAND ITALIA
 Annex: Certificate No. MED 31009 issued by Kiwa Cermet Italia S.p.A.

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